## THE UNITED STATES DISTRICT COURT FOR DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC., and ARIUS TWO, INC.,

Plaintiffs,

v.

Civil Action No. 18-1395-CFC

ALVOGEN PB RESEARCH & DEVELOPMENT LLC, ALVOGEN MALTA OPERATIONS LTD., ALVOGEN PINE BROOK LLC, ALVOGEN, INC., and ALVOGEN GROUP, INC.,

Defendants.

BIODELIVERY SCIENCES INTERNATIONAL, INC., and ARIUS TWO, INC.,

Plaintiffs,

v.

Civil Action No. 1:19-cv-444-CFC

CHEMO RESEARCH S.L., INSUD PHARMA S.L.U., INTELGENX CORP., and INTELGENX TECHNOLOGIES CORP.,

Defendants.

## **JOINT STIPULATION**

This stipulation is made by and between Plaintiffs BioDelivery Sciences International, Inc. ("BDSI") and Arius Two, Inc. (collectively, "Plaintiffs"), Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen

Pine Brook LLC, Alvogen, Inc., and Alvogen Group, Inc. (collectively, "Alvogen"), and Defendants Chemo Research, S.L., Insud Pharma S.L., Intelgenx Corp., and Intelgenx Technologies Corp. (collectively "Chemo") (Alvogen and Chemo collectively referred to as "Defendants") (Plaintiffs, Alvogen, and Chemo collectively as "Parties" and individually each as "Party").

WHEREAS, as part of discovery in the above-captioned consolidated action, Plaintiffs produced to Defendants documents submitted to the FDA, i.e. Investigational New Drug Application No. 72,428 and New Drug Application No. 207932 set forth in Exhibit A.

WHEREAS, the Parties have met and conferred and have determined that stipulating to the authenticity pursuant to Rule 901 of the Federal Rules of Evidence and non-hearsay business record status pursuant to Rule 803(6) of the Federal Rules of Evidence of the documents set forth in Exhibit A will avoid significant and unnecessary burden and expense on each Party.

NOW THEREFORE, the Parties, by and through their respective undersigned counsel in the above-captioned consolidated case, and subject to the approval of the Court, stipulate and agree as follows:

- The documents set forth in Exhibit A below are (a) authentic pursuant to Rule 901 of the Federal Rules of Evidence and (b) non-hearsay business records that satisfy all the elements of Rule 803(6) of the Federal Rules of Evidence.
- 2. The Parties reserve the right to object to the introduction into evidence of the above referenced documents (in whole or in part) on all other

grounds, including the admissibility of these documents for reasons other than challenging their authenticity under Rule 901 of the Federal Rules of Evidence, their non-hearsay status, or their satisfaction of the elements of Rule 803(6) of the Federal Rules of Evidence.

3. Except as expressly addressed herein, this stipulation does not affect the Parties' right to object to the admissibility of any other testimony, evidence, document, or thing under any ground(s) permitted by law.

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SO ORDERED this day of, 202	20.
_	UNITED STATES DISTRICT JUDGE

## **EXHIBIT A**

Production No.	
BEL00009469-BEL00009573	
BEL00010689-BEL00010707	
BEL00011440-BEL00011602	
BEL00014328-BEL00014345	
BEL00364625-BEL00364794	
BEL00135687-BEL00135878	
BEL00014722-BEL00014737	
BEL00047826-BEL00047860	
BEL00047887-BEL00047929	
BEL00053713-BEL00053719	
BEL00015333-BEL00015335	
BEL00053725-BEL00053728	
BEL00053729-BEL00053760	
BEL00053761-BEL00053836	
BEL00053837-BEL00053838	
BEL00058286-BEL00058287	
BEL00058288-BEL00058289	
BEL00058291-BEL00058292	
BEL00058408-BEL00058435	
BEL00036219	
BEL00052579 (native)	
BEL00068394-BEL00068395	
BEL00054576-BEL00054809	
BEL00058682 (native)	
BEL00054021 (native)	

Production No.
BEL00054022 (native)
BEL00054023-BEL00054309
BEL00059559 (native)
BEL00059739-BEL00061145
BEL00091067-BEL00091100
BEL00421081-BEL00421236
BEL00096779-BEL00096859
BEL00096863-BEL00096868
BEL00016043-BEL00018913
BEL00014532-BEL00014721
BEL00193535-BEL00193658
BEL00015743-BEL00015812
BEL00040734-BEL00040824
BEL00040825-BEL00040906